IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JUDITH MAHER, Plaintiff, v. GUIDANT CORPORATION and GUIDANT SALES CORPORATION, Defendants.	Case No. 07 C 6561 Honorable Judge John Nordberg Magistrate Judge Sidney Schenkier

DEFENDANTS GUIDANT CORPORATION AND GUIDANT SALES CORPORATION'S ANSWER TO PLAINTIFF'S COMPLAINT AT LAW

Defendants Guidant Corporation[1] and Guidant Sales Corporation ("GSC") (collectively "Defendants") answer Plaintiff's Complaint at Law ("Complaint") as follows:

Plaintiff's Complaint improperly mixes factual averments with argumentative rhetoric so as to make admissions or denials of such averments difficult or impossible. Accordingly, by way of a general response, all allegations are denied unless specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, or speculations which are contained in the averment or in the Complaint as a whole.

1. Defendants admit that Guidant Corporation has offices in Indianapolis, Indiana. Defendants deny the remaining allegations of Paragraph 1.

2. Defendants admit that GSC distributes and sells the product that is at issue in this Complaint. Defendants state that GSC has offices in Indianapolis, Indiana and that GSC is a

[1] Cardiac Pacemakers, Inc. and its related entities designed and manufactured the medical device at issue in this case, and Guidant Sales Corporation sold the medical device at issue in this case. Guidant Corporation played no part in the design, manufacture, distribution, and/or sale of the device at issue in this case. Accordingly, Guidant Corporation is an improper party to this lawsuit and should be dismissed.

wholly-owned subsidiary of Cardiac Pacemakers, Inc. ("CPI"). Defendants deny the remaining allegations of Paragraph 2.

3. Defendants admit upon information and belief that in or around September 1998, Plaintiff Judith Maher was implanted with a DISCOVERY DDRO Model 1274 pacemaker, serial number 403115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 3 and, therefore, deny the same.

4. Defendants incorporate by reference their answers to the allegations of Paragraphs 1 through 3.

5. Defendants admit that GSC sells medical devices, including the DISCOVERY DDRO Model 1274 pacemaker. Defendant Guidant Corporation denies that it designs, tests, manufactures, or provides labeling for pacemakers or any medical devices. Defendants state that CPI designs, tests, manufactures, and provides labeling for pacemakers and other medical devices, including the DISCOVERY DDRO Model 1274. Defendants deny the remaining allegations of Paragraph 5.

6. Defendants state that pacemakers, including the DISCOVERY DDRO Model 1274, are intended to administer therapy to patients with serious underlying heart conditions. Defendants further state that pacemakers are complex mechanical devices and the allegations of Paragraph 6 do not completely characterize the features or functioning of these devices.

7. Defendants admit upon information and belief that Plaintiff Judith Maher was implanted with a DISCOVERY DDRO Model 1274 pacemaker, serial number 403115, and that on or about October 19, 2005, Plaintiff Judith Maher's DISCOVERY DDRO Model 1274 pacemaker was explanted. Defendants deny the remaining allegations of Paragraph 7.

8. Defendants admit that the DISCOVERY DDRO Model 1274 pacemaker was the subject of a July 18, 2005 letter to physicians and that the FDA has classified this action as a recall. Defendants further admit that Paragraph 8 purports to quote selectively and/or paraphrase the July 18, 2005 letter to physicians. Defendants state that the complete and precise content of that letter can be ascertained from the letter itself. Defendants deny Plaintiff's characterization of the letter and deny the remaining allegations of Paragraph 8.

9. Defendants admit that Paragraph 9 purports to quote selectively and/or paraphrase a July 18, 2005 letter to physicians. Defendants state that the complete and precise content of that letter can be ascertained from the letter itself. Defendants deny the remaining allegations in Paragraph 9.

10. Defendants deny the allegations of Paragraph 10.

COUNT I - NEGLIGENCE

11. Defendants incorporate by reference their answers to the allegations of Paragraphs 1 through 10.

12. Defendants deny the allegations of Paragraph 12.

13. Defendants deny the allegations of Paragraph 13.

14. Defendants deny the allegations of Paragraph 14.

15. Defendants deny the allegations of Paragraph 15.

16. Defendants deny the allegations of Paragraph 16.

Defendants deny that Plaintiff is entitled to the relief requested in the Wherefore clause following Paragraph 16 or to any relief whatsoever.

COUNT II—STRICT LIABILITY

17. Defendants incorporate by reference their answers to the allegations of Paragraphs 1 through 16.

18. Defendants deny the allegations of Paragraph 18.

19. Paragraph 19 asserts legal conclusions to which no response is required. To the extent a response is required, Defendants state that they have complied with all applicable legal duties and deny the allegations of Paragraph 19.

20. Defendants deny the allegations of Paragraph 20.

21. Defendants deny the allegations of Paragraph 21.

22. Defendants deny the allegations of Paragraph 22.

23. Defendants deny the allegations of Paragraph 23.

24. Defendants deny the allegations of Paragraph 24.

Defendants deny that Plaintiff is entitled to the relief requested in the Wherefore clause following Paragraph 24 or to any relief whatsoever.

COUNT III – BREACH OF WARRANTY

25. Defendants incorporate by reference their answers to the allegations of Paragraphs 1 through 24.

26. Defendants deny the allegations of Paragraph 26.

27. Defendants deny the allegations of Paragraph 27.

28. Defendants deny the allegations of Paragraph 28.

Defendants deny that Plaintiff is entitled to the relief requested in the Wherefore clause following Paragraph 28 or to any relief whatsoever.

AFFIRMATIVE AND OTHER DEFENSES

Having answered the allegations of Plaintiff's Complaint and having denied any liability whatsoever, Defendants further deny allegations that have not been expressly admitted and assert the following affirmative defenses.

FIRST AFFIRMATIVE DEFENSE

At no time has Guidant Corporation participated in any way in the design, manufacture, assembly, marketing, or sale of the products described in Plaintiff's Complaint. Guidant Corporation is an improper party to this action and should be dismissed.

SECOND AFFIRMATIVE DEFENSE

Defendant Guidant Corporation states that it never designed, manufactured, advertised or sold the medical devices at issue in this litigation in the State of Illinois, or anywhere else. This Court lacks personal jurisdiction over Guidant Corporation and any assertion of personal jurisdiction over Guidant Corporation violates its rights under the Due Process Clause of the Fourteenth Amendment of the United States Constitution.

THIRD AFFIRMATIVE DEFENSE

The devices to which Plaintiff refers in the Complaint are Class 3 prescription medical products. The federal government has preempted the field of law applicable to the design, testing, and labeling of prescription medical products. Plaintiff's causes of action, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

FOURTH AFFIRMATIVE DEFENSE

At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended

use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and the state-of-the-art in existence at the time.

FIFTH AFFIRMATIVE DEFENSE

The devices at issue in this case are prescription medical products that fall within the "comment k" and "comment j" exceptions to strict liability, as defined in Restatement (Second) of Torts §402A. The benefits of the devices outweigh the risks, if any, which may be attendant to their use. The devices are therefore neither defective nor unreasonably dangerous.

SIXTH AFFIRMATIVE DEFENSE

The devices at issue in this case are prescription medical products that fall within Restatement Third, Torts: Products Liability § 6. Therefore, the devices are reasonably safe in design if a reasonable healthcare provider would prescribe the devices for any class of patients knowing the foreseeable risks and therapeutic benefits.

SEVENTH AFFIRMATIVE DEFENSE

Under the learned intermediary defense, the manufacturer of a prescription medical device is to provide warnings and appropriate information only to the prescribing physician and the medical profession, which act as "learned intermediaries" in determining the use of the product for a particular patient. To the extent Plaintiff asserts that Defendants failed to provide Plaintiff with adequate warnings regarding the use of the device, any obligation to warn was discharged when adequate warnings were provided to Plaintiff's treating and prescribing physicians. Plaintiff's claims are also barred by the Sophisticated User Doctrine, or similar applicable laws.

EIGHTH AFFIRMATIVE DEFENSE

Defendants believe, and upon that ground allege, that Plaintiff was advised of the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, or comparative fault, this conduct bars, in whole or in part, the damages that Plaintiff seeks to recover herein.

NINTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiff, if any, may have resulted from an intervening cause or causes, and any action on the part of Defendants was not the proximate cause of Plaintiff's alleged injuries.

TENTH AFFIRMATIVE DEFENSE

The conduct of Defendants and the subject products conformed with the Federal Food, Drug, and Cosmetic Act and the requirements of the Food and Drug Administration. Moreover, Defendants' activities conformed with state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred because Plaintiff suffered no injury or damages as a result of the alleged conduct and does not have any right, standing, or competency to maintain claims for damages or other relief.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred, in whole or in part, by the applicable statutes of limitations and statutes of repose.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred, in whole or in part, by the doctrines of waiver, estoppel, and laches.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's breach of warranty claims are barred because there is no privity of contract between Plaintiff and Defendants; Plaintiff failed to give timely notice of any alleged breach of warranty to Defendants; Plaintiff did not reasonably rely upon any alleged warranty; Plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged injuries occurred, if at all, because of circumstances and conditions beyond the control of Defendants.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because any labeling with respect to the subject product was not false or misleading and, therefore, constitutes protected commercial speech under the applicable provisions of the United States Constitution, the Illinois Constitution, and the constitutions of the other forty-nine states.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution because they purport to regulate interstate commerce and impermissibly place an undue burden on interstate commerce.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims fail to state a cause of action and fail to state claims for which relief may be granted.

TWENTIETH AFFIRMATIVE DEFENSE

The claims asserted in the Complaint are barred, in whole or in part, because the utility of the devices at issue outweighs the alleged risk.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Defendants are entitled to a credit for any settlement of claims for alleged injuries and damages made by Plaintiff with any other person or entity.

TWENTY-SECOND AFFIRMATIVE DEFENSE

To the extent that the claims asserted in the Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the Illinois Constitution.

TWENTY-THIRD AFFIRMATIVE DEFENSE

At all relevant times herein, Plaintiff's prescribing physicians were in the position of a sophisticated purchaser, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Defendants assert any and all defenses that might apply to this action by virtue of applicable Illinois law.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action should be dismissed pursuant to the doctrine of *forum non conveniens*.

Defendants expressly reserve the right to amend this Answer to assert additional defenses or to make additional claims for relief as discovery in this action should warrant.

JURY DEMAND

Defendants hereby demand a trial by jury in this case.

PRAYER FOR RELIEF

WHEREFORE, Defendants pray for relief from judgment from Plaintiff as follows:

1. Plaintiff takes nothing by reason of this Complaint;
2. Defendants recover their costs and attorneys' fees incurred herein;
3. For a trial by jury on all issues so triable; and
4. For such further and other relief as the Court deems proper.

Respectfully submitted,

/s/ John A. Roberts
One of the Attorneys for Defendants Guidant Corporation and Guidant Sales Corporation

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 29, 2007, a true and correct copy of the foregoing Defendants Guidant Corporation and Guidant Sales Corporation's Answer to Plaintiff's Complaint at Law was sent via U.S. mail, postage pre-paid, to the following:

Scott A. Kogen
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/s/ John A. Roberts
One of the Attorneys for Defendant Guidant Corporation and Guidant Sales Corporation

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